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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,225	03/26/2001	Peter Hawkins	109068	5800

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ALEXANDRIA, VA 22320

EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/816,225

Applicant(s)

HAWKINS ET AL.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Amendment Entry & Claim Status***

The amendment filed on August 04, 2005 has been acknowledged and entered.

***Withdrawn Rejection(s)***

Rejection under 112, 1<sup>st</sup> paragraph is withdrawn herein.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-11, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kritz et al. (US 6,110,660) in view of Rapoport (US 5,978,694) and further in view of Simpson (US 3,858,111).

Kritz teaches a method of detecting an analyte comprising the steps of providing a sample comprising a marker, a binder (recognition element), said marker having material comprising an externally, inductively detectable relative magnetic permeability constant of at least about 600, said recognition element binds to or competes for binding with the analyte, said marker and said recognition element induce in a transducer comprising a coil a first inductance value when said analyte is absent from said sample and a second inductance value when said analyte is present in said sample. The recognition element (binder) is immobilized to a matrix (substrate) – see

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col. 6, lines 36-37. The sample containing the analyte and marker are added to the carrier. A competition or a sandwich reaction formed. The reaction was placed in a measuring coil and inductance changes noted. The inductance change in turn affected either the resonance frequency for an LC-circuit in which the coil was a part, or the balancing expressed as a voltage response, in a Maxwell Bridge in the coil was a part. The relationship between the change of resonance frequency in Hz, or the voltage difference in mV, is a linear relationship against the number of particles in the measuring solution, expressed as iron concentration. The molecular layer (recognition element) comprises an antibody/antigen and the second molecules are antigens or antibodies. (see col. 3, line 10-col. 4, lines 47; col. 5, line 10-col. 6, line 42; col. 9, lines 1-4).

However, Kritz does not teach measuring the difference in resonant frequency when the substrate is exposed to a magnetic field and when the substrate is not exposed to the magnetic field; a solenoid coil.

Rapoport teaches a method for detecting in a sample a substance that responds to an applied magnetic field, such as paramagnetic substance. The sample is placed in an applied magnetic field, and the effect of the sample on a performance characteristic of a first electrical conductor is measured by the first measuring means and the value is displayed and/or optionally inputted to a data storage and analysis means. Subsequent measurements of this same performance characteristic of the first electrical conductor are made over time, either continuously or at pre-determined intervals. The performance characteristics are inductance, capacitance, etc. (See col. 3, lines 35-37).

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It is also desirable to compare the effect of the sample on the conductor in the presence of the applied magnetic field with the effect of the sample on the conductor in the absence of the applied magnetic field. (see col. 3, lines 20-26). Rapoport teaches a solenoid coil (figure 1).

It would have been obvious to one of ordinary skills in the art to measure the performance characteristic such as inductance of the sample in the presence and absence of the applied magnetic field as taught in Rapoport in the method of Kritz because that way the two measurements can be compared, taking into consideration the calibrations necessary to account for the differences, if any, in the performance characteristic of the first and second conductors. The corrected difference between the two measurements is then a function solely of the presence of a substance in the sample, which responds to the applied magnetic field.

However, Kritz and Rapoport fail to teach determining the difference in resonance frequency of a tuned circuit which is connected to a phase locked loop comprising a driver which generates a driving signals for driving the tuned circuit, and a phase comparator for determining the phase difference between the driving signal and an output signal obtained from the tuned circuit, the difference in resonance frequency being determined by monitoring the performance of the phase locked loop.

Simpson teaches an apparatus for the measurement of absolute and relative concentration of chemical substances in processes wherein the nuclei of the substances being measured have defined magnetic moments. The apparatus in fig. 1 comprises a tuned circuit (13) comprising a driver (16) for driving signals for driving the

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tuned circuit. The tuned circuit is connected to phase locked loop (which include the phase sensitive detector, the lock in detector, the RF oscillator) comprising a lock-in detector or phase comparator (26). The lock-in detector represents the difference in phase between the reference signal from oscillator 10 and signal from the tuned circuit 13. (see col. 4, line 24-col. 5, line 27). Simpson also teaches that the apparatus is used for concentration measurements of nuclei having magnetic moments in different types of processes. (see col. 9, lines 40-44).

It would have been obvious to one of ordinary skills in the art to use the apparatus of Simpson to measure the resonance frequency difference according to the method of Kritz and Rapoport because Simpson teaches that his apparatus is useful in measuring the concentrations of nuclei having magnetic moments in different types of processes and Kritz combined Rapoport teach a method of determining the concentration of chemical process of magnetic particles having magnetic moments. Tuned circuit is used to measure the resonance frequency or the signal induced by the magnetic field applied to the sample. Phase lock loop generates an error signal and compares the references signal with the signal produced by the tuned circuit thereby provides a final output signal indicative of the frequency difference.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kritz et al. (US 6,110,660) in view of Rapoport (US 5,978,694) further in view of Simpson as applied to claim 9 above further in view of Houghton et al. (US 5,679,342).

Kritz and Rapoport and Simpson have been discussed above.

However, Kritz and Rapoport and Simpson fail to teach a plastic strip as the substrate.

Houghton et al. teaches an assay wherein the receptor layer is immobilized on a matrix/solid support such as plastic strips, microliter plates, or any surface onto which antigen may be immobilized.(See col. 19, lines 45-51).

It would have been obvious to one of ordinary skills in the art that using matrix/solid support such as plastic strips is well known in the art. Thus, one of ordinary skills in the art would find it obvious to use plastic strips as taught by Houghton in the modified method of Kritz and Rapoport and Simpson since Kritz suggested that the receptors are immobilized to a matrix and it is well known in the art that matrix for immobilizing receptor can be plastic strips for these plastic strips are polymers with compatible functional groups that immobilize the receptors securely on the strips and do not interfere with the molecular interaction of the receptor and the target analyte.

### ***Conclusion***

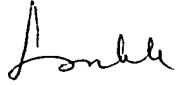
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do  
Patent Examiner  
January 6, 2006

  
**LONG V. LE**  
**SUPERVISORY PATENT EXAMINER**  
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01/09/06